# In the United States Court of Federal Claims office of special masters

No. 13-960V Filed: June 30, 2015

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ERIC WATERMAN and TAREE	*	
WATERMAN, as parents and natural	*	Special Master Hamilton-Fieldman
Guardians of A.T.W., a minor, deceased,	*	-
	*	
Petitioners,	*	Ruling on the Record; Decision Denying
	*	Entitlement; Polio Vaccine; Diphtheria,
V.	*	Tetanus, and Pertussis ("DTAP") Vaccine;
	*	Hepatitis B Vaccine; Pneumococcal Vaccine
SECRETARY OF HEALTH	*	("Prevnar"); Rotavirus Vaccine ("Rotateq");
AND HUMAN SERVICES,	*	Haemophilus influenzae type B ("HiB")
	*	Vaccine; Injuries Resulting in Death.
Respondent.	*	-
* * * * * * * * * * * * * * * *	*	

<u>Lorraine J. Mansfield</u>, Law Office of Lorraine Mansfield, Las Vegas, NV, for Petitioners. <u>Gordon Shemin</u>, U.S. Department of Justice, Washington, DC, for Respondent.

# DECISION<sup>1</sup>

On December 6, 2013, Eric Waterman and Taree Waterman ("Petitioners") filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("the Program"), 42 U.S.C. §300aa-10 *et seq.* (2006),<sup>2</sup> on behalf of their minor child, A.T.W. Petitioners allege that, as a result of the administration of Polio; Diphtheria, Tetanus, and

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<sup>&</sup>lt;sup>1</sup> Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this ruling on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction "of any information furnished by the party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id*.

<sup>&</sup>lt;sup>2</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§300aa-10 *et seq.* (2006). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. §300aa.

Pertussis ("DTAP"); Hepatitis B; Haemophilus influenzae type B ("HiB"); Pneumococcal ("Prevnar"); and Rotavirus ("Rotateq") vaccines on August 20, 2013, A.T.W. suffered injuries that resulted in his death. Petition (Pet.) at 1–2. For the reasons set forth below, the undersigned finds that the record does not support entitlement to an award under the Program.

#### PROCEDURAL HISTORY

In addition to their petition, Petitioners filed ten exhibits – including medical records, two affidavits, and a VAERS Report – on December 6, 2013. *See* Petitioners' Exhibits ("Pet. Ex.") 1-10.<sup>3</sup> On February 12, 2014, Petitioners filed an Autopsy Report, a toxicology report, and a Medical Examiner's Report (Petitioners' Exhibits (Pet. Ex.) 11, 12, and 13, respectively); on March 13, 2014, they filed a police report (Pet. Ex. 14); and on March 18, 2014, they filed an expert report authored by pediatrician Leroy Bernstein (Pet. Ex. 15). In his report, Dr. Bernstein opines that "[t]he multiple vaccination [sic] administered to infant [A.T.W.] was a possible cause of death. To my reasonable knowledge, the six vaccines administered the same day could have caused a reaction which caused his death." Pet. Ex. 15 at 2. Petitioners filed a statement of completion on March 19, 2014.

At a status conference held on March 25, 2014, the undersigned encouraged Petitioners' counsel to file a supplemental expert report that articulated the nature of the injury allegedly caused by the vaccinations. The undersigned explained that, if A.T.W. did not suffer an alleged injury that qualified as an encephalopathy or anaphylaxis under the Vaccine Table ("Table"), causation would not be presumed, and Petitioners would be required to make an argument regarding causation-in-fact. The undersigned also clarified that death, in and of itself, is not a Table injury, though it may be a sequela of a Table injury.

On April 17, 2014, Respondent filed a Rule 4(c) Report ("Report"). In the Report, Respondent argued that Petitioners had not alleged a Table injury, and that Petitioners had failed to "establish a more likely than not causal connection between A.T.W.'s vaccinations on August 20, 2013, and his subsequent death later that night." Report at 10. Respondent argued that "Dr. Bernstein's report is insufficient to meet petitioners' burden in that it does not offer a reliable medical theory causally connecting any of the vaccinations A.T.W. received to an injury that resulted in death." *Id*.

On June 10, 2014, Petitioners filed Exhibit 17, entitled "L. Bernstein, M.D. Report." The entirety of Dr. Bernstein's supplemental report consists of the following sentences: "The baby possibly would not have died had he not received multiple vaccinations on the same day. The vaccinations could have been a factor. Medicine is an imperfect science. No doctor could state

When these exhibits were uploaded to the electronic docket, Exhibit 5 was inadvertently omitted. All page references to these exhibits will be to the originally filed versions rather than the electronic versions.

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<sup>&</sup>lt;sup>3</sup> Petitioners' Exhibits 1 through 10 were originally filed on paper, attached to the petition. When these exhibits were uploaded to the electronic docket. Exhibit 5 was inadvertently or

conclusively that the vaccination caused the baby's death." Pet. Ex. 17 at 1. Dr. Bernstein attached to his report an article published in the Journal of Human & Experimental Toxicology. Pet. Ex. 17 at 2-11. The article concludes, based on the studied epidemiology, that "nations that require more vaccine doses tend to have higher infant mortality rates." Pet. Ex. 17 at 11. The article's authors do not attempt to identify a causal mechanism for these infants' deaths.

Also on June 10, 2014, the undersigned convened a second status conference during which the undersigned reiterated that Petitioners had yet to file an expert report that articulated a theory of causation or identified the type of reaction being alleged. The undersigned referred Petitioners' counsel to the seminal case of *Althen v. Sec'y of Health and Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). Petitioners' counsel opined that Dr. Bernstein's supplemental expert report was sufficient to meet the requirements of *Althen*.

A third and final status conference was held on August 14, 2014. During the status conference, Respondent argued, as she had in her Rule 4 Report, that a "possible" causal connection between the vaccines and the alleged injury is insufficient to prove causation under *Moberly v. HHS*, 592 F.3d 1315, 1322 (Fed. Cir. 2010). The undersigned again reiterated that a temporal connection between vaccination and injury is insufficient, without a causal theory, to prove causation under *Althen*. Acknowledging these comments, Ms. Mansfield indicated that Petitioners intended to rely on their previously filed expert reports. Because Petitioners were disinclined to file additional documentation regarding their causal theory, the undersigned set deadlines for the parties to file motions regarding how to proceed on the then-existing record.

On September 11, 2014, Respondent filed a Motion for Ruling on the Record or, in the alternative, for Summary Judgment ("Resp't's Mot."). Petitioners filed Petitioner's Response to Motion for Ruling on the Record or in the Alternative for Summary Judgment ("Pet. Resp.") on September 29, 2014. Respondent filed a Reply to Response to Motion for Ruling on the Record or in the Alternative for Summary Judgment ("Resp't's Rep.") on October 10, 2014. This case is now ripe for a decision on the record.

#### FACTUAL HISTORY

Petitioners' child, A.T.W., was born at term on June 11, 2013. Pet. Ex. 4 at 6-7. A.T.W. was healthy at birth and the pregnancy was "uncomplicated." *Id.* at 4; *see generally* Pet. Ex. 5 at 5, Pet. Ex. 13 at 4. Ms. Waterman would later report to the police that, prior to immunization, "he had been very healthy with the exception of some previous slight jaundice." Pet. Ex. 13 at 2.

A.T.W. received six vaccinations – DTAP, Hep B, Polio, HiB, Prevnar, and Rotateq – during an August 20, 2013 well-child check-up. Pet. Ex. 6 at 18. A.T.W. was two months old at

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<sup>&</sup>lt;sup>4</sup> Neil Miller and Gary Goldman, *Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity?*, 30(9) Hum Exp Toxicol 1420-28 (2011).

the time of vaccination. *Id.* During the check-up, A.T.W. was noted to have been healthy, except for a possible heart murmur for which he was referred to a cardiologist, and he "appear[ed] to be in no acute distress." Pet. Ex. 6 at 2-3; Pet. Ex. 13 at 4.

The records filed by Petitioners are internally contradictory regarding A.T.W.'s health and behavior during the afternoon following vaccine administration. After A.T.W.'s death, Taree Waterman reported to police that "[h]e appeared to tolerate the [two month well-check] appointment and the rest of the day with no apparent distress or complications .... He was eating, sleeping, and having normal bowel movements." Pet. Ex. 13 at 4. In the affidavit filed in support of his vaccine claim, however, Eric Waterman noticed that, during the afternoon of August 20, 2013, A.T.W. "seemed different from his normal appearance and behavior," taking half of his usual bottle and appearing sleepy. Pet. Ex. 9 at 2. According to Eric Waterman's vaccine claim affidavit, he took three ounces of his bottle and went down to sleep between 8:00 and 8:30 p.m.; according to Taree Waterman's affidavit, A.T.W. "looked as though he was still sleeping by 7:00p.m.," took only three (3) ounces of his bottle instead of his usual six (6) ounces," and "went down to sleep between 8:00 and 8:30 p.m.;" according to Taree Waterman's statements to police, A.T.W. took approximately 4 ounces of formula at 7:00 p.m., then fell asleep. *Compare* Pet. Ex. 9 at 2, 5; Pet. Ex. 13 at 4.

At approximately 11:00 p.m., Mr. Waterman observed that A.T.W.'s skin appeared "pale and mottled," that his body was "stiff and abnormal," that he was "wheezing and seemed to have difficulty breathing," and that he was lying face down with vomit around his nose and mouth. Pet Ex. 9 at 2, 5; Pet. Ex. 11 at 1. Family members called 911 at approximately 11:05 p.m., and Mr. Waterman began CPR while awaiting the ambulance. Pet. Ex. 9 at 2, 5-6. Attempts to resuscitate A.T.W. failed, and A.T.W. was pronounced dead at the hospital. Pet. Ex. 8 at 2.

A.T.W.'s autopsy report concludes that A.T.W.'s manner of death was natural and the cause of death was Sudden Infant Death Syndrome ("SIDS"). Pet. Ex. 11 at 1. The autopsy found scattered petechiae of the thymus, epicardial surface and visceral pleura; a bilateral pulmonary edema; and bilateral pulmonary congestion. *Id.* The coroner noted that A.T.W. had received "an Octavalent Vaccination" on August 20, 2013, but concluded that "the current medical literature does not support such a causal connection to a reasonable degree of medical certainty." *Id.* 

#### APPLICABLE LEGAL STANDARDS

To receive compensation under the Program, Petitioners must prove either: (1) that the A.T.W. suffered a "Table Injury" – i.e., an injury included in the Vaccine Injury Table – corresponding to his vaccinations, or (2) that A.T.W. suffered an injury that was actually caused by his vaccination. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-(11)(c)(1). Pursuant to Vaccine Rule 8(d), "[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." *See* Vaccine Rule 8(d).

To establish that a Table Injury occurred as a result of a vaccination, Petitioners must demonstrate the occurrence of a Table Injury, meaning that the injury is one of the types of injuries enumerated in the Vaccine Injury Table, the injury corresponds to the vaccination A.T.W. received, and the injury occurred within the appropriate time period following the vaccination specified by the Table. *See* 42 U.S.C. §§ 300aa-11(c)(1), 300aa-13(a)(1)(A). If Petitioners meet this burden, then the Table Injury is presumed to have been caused by the vaccination and Petitioners are entitled to compensation absent a showing by Respondent that the injury was caused by some factor other than the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B). If the medical records do not disclose a diagnosis of a Table Injury, Petitioners must submit a medical expert's opinion interpreting A.T.W.'s symptoms as a Table injury. *See Schneider v. Sec'y of Health and Human Servs.*, 2005 WL 318697 at \*2 (Fed. Cl. Feb. 1, 2005) (denying the existence of a Table Injury where no medical expert has opined such an injury occurred). A lay opinion that a Table Injury occurred is not sufficient to establish that a Table injury in fact occurred. *Id.* 

Petitioners may also seek compensation for a non-Table injury by establishing that the vaccine caused-in-fact A.T.W.'s injury. To establish causation in fact, Petitioners must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A). Petitioners are required to prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health and Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health and Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999). In the seminal case of *Althen v. Sec'y of Health and Human Servs.*, the Federal Circuit set forth a three-prong test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *Althen v. Sec'y of Health and Human Servs.*, 418 F.3d at 1278. The *Althen* test requires the petitioner to set forth: "(1) a medical theory causally connecting the vaccine and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* To establish entitlement to compensation under the Program, Petitioners are required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.* 

Specifically, under the first prong of *Althen*, Petitioners must offer a scientific or medical theory that answers in the affirmative the question "can the vaccine(s) at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health and Human Servs.*, No. 01-0165V, 2004 WL 1717359, at \*4 (Fed. Cl. Spec. Mstr. July 16, 2004). This prong may be satisfied in a number of ways, for instance, by "providing evidence that at least a sufficient minority in the medical community has accepted the theory, [so] as to render it credible." *Id.* In addition, epidemiological studies and an expert's experience, while not dispositive, lend significant credence to the claim of plausibility; articles published in respected medical journals, which have been subjected to peer review, are also persuasive. *Id.* However, publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been

published." *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593–94 (1993) (emphasis in original)).

Under *Althen*'s second prong, Petitioners must prove that the vaccine actually *did* cause the alleged injury in a particular case. *See Pafford*, 2004 WL at \*4; *Althen*, 418 F.3d at 1278. Petitioners do not meet this obligation by showing only a temporal association between the vaccination and the injury; rather, Petitioners must explain how and why the injury occurred. *Pafford*, 2004 WL at \*4. In order to explain how an injury occurred, Petitioners must advance a medical theory with a logical sequence of cause and effect demonstrating the vaccine was the reason for the injury. *Id*. (citing *Grant v. Sec'y of Health and Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Under the third prong of *Althen*, Petitioners must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. Where a petitioner's expert views the temporal relationship as the "key" indicator of causation, the claim must fail. *See*, *e.g.*, *Grant*, 956 F.2d at 1148 (holding that a lack of direct evidence of causation is weighted more strongly than a temporal relationship); *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) (holding that inoculation is not the cause of every event that occurs within a ten-day period following it); *Thibaudeau v. Sec'y of Health and Human Servs.*, 24 Cl. Ct. 400, 403 (Oct. 23, 1991).

#### DISCUSSION

In this case, Petitioners seek compensation for A.T.W.'s death under multiple theories: 1) as a sequela of the Table Injury anaphylaxis; 2) as a sequela of the Table Injury encephalopathy, and 3) under an off-Table injury theory. The undersigned now finds that Petitioners are not entitled to compensation under the Program.

#### A. Table Injuries

# 1. Anaphylaxis

Petitioners' first theory is that A.T.W.'s death occurred as a sequela of anaphylaxis from the DTAP, IPV (Polio), or Hepatitis B vaccine. Pet. Resp. at 4–7, 9-10. Anaphylaxis is listed on the Vaccine Injury Table as a covered condition for the DTAP, IPV (Polio), and Hepatitis B vaccines. 42 C.F.R. § 100.3(a). However, the time period for the first symptom or manifestation of onset of anaphylaxis for any vaccine for which anaphylaxis is a covered condition is four

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<sup>&</sup>lt;sup>5</sup> Petitioner does not specify which vaccine caused the alleged anaphylaxis, but rather inserted into Petitioner's response the portions of the Vaccine Injury Table that correspond to the vaccines A.T.W. received for which anaphylaxis is a covered condition. Pet. Resp. at 5–8, ECF No. 23.

hours or less. *Id.* Anaphylaxis is "an acute, severe, and potentially lethal systemic allergic reaction" that begins "minutes to a few hours after exposure." 42 C.F.R. § 100.3(b)(1).

A.T.W. received the vaccinations at approximately 11:20 a.m. Pet. Ex. 9 at 2, 5. Eight hours later, between 7:00 and 8:30 p.m., A.T.W. was put down to sleep, and was discovered in distress around 11:00 p.m. *Id.*; Pet. Ex. 13 at 2. Although A.T.W.'s behavior may have been somewhat different from normal on the afternoon following vaccination, *see* Pet. Ex. 9 at 2, 5 (noting that A.T.W. took half of his usual bottle and appeared sleepy), he was not suffering from an "acute, severe reaction" until approximately twelve hours after vaccine administration. *See id.* A.T.W.'s acute distress occurred far too long after the vaccinations to be considered anaphylaxis. *See Hellenbrand-Sztaba v. Sec'y of Health and Human Servs.*, No. 91-572V, 1995 WL 650678 at \*4-5 (Fed. Cl. Spec. Mstr. Oct. 19, 1995) (holding that death was not a sequela of anaphylaxis where death occurred more than 14 hours after a DPT vaccination and no symptoms of an allergic reaction had manifested prior to the child's death during sleep). Further, neither A.T.W.'s treating physicians nor Dr. Bernstein diagnosed A.T.W. as suffering from anaphylaxis.

For these reasons, the undersigned finds that Petitioners have failed to prove that A.T.W. suffered from anaphylaxis, as defined by the Table, or that A.T.W.'s death was a sequela of such anaphylaxis.

# 2. Encephalopathy

Petitioners' second theory is that A.T.W.'s death occurred as a sequela of encephalopathy from the DTAP vaccine. Encephalopathy is listed on the Vaccine Injury Table as a covered condition for the DTAP vaccine.<sup>6</sup> 42 C.F.R. § 100.3(a). The applicable time period for the first symptom or manifestation of onset of encephalopathy is 72 hours or less. *Id.* Encephalopathy in children less than 18 months of age without any corresponding seizures is indicated by a "significantly decreased level of consciousness." 42 C.F.R. § 100.3(c)(2)(i)(A). A significantly decreased level of consciousness is present when there is decreased or absent response to the environment (responds, if at all, only to loud voice or painful stimuli), decreased or absent eye contact (failure to fix gaze upon family members or other individuals), or inconsistent or absent responses to external stimuli (failure to recognize familiar people or things). 42 C.F.R. § 100.3(b)(2)(i)(D). According to the Vaccine Injury Table, the following symptoms are not enough, standing alone, to rise to the level of acute encephalopathy: sleepiness, irritability (fussiness), high-pitched and unusual screaming, and poor feeding. 42 C.F.R. § 100.3(b)(2)(i)(E).

There is no evidence in the record that A.T.W. had symptoms of encephalopathy. Encephalopathy is a disease of the brain, and the autopsy indicates nothing abnormal about A.T.W.'s brain. *See generally* Pet. Ex. 11. Moreover, although A.T.W. was found in distress,

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<sup>&</sup>lt;sup>6</sup> Petitioners do not explicitly argue that A.T.W. suffered from encephalopathy as a result of the DTAP vaccine. They do, however, refer to the DTaP portion of the Vaccine Injury Table, which lists encephalopathy as a covered condition. Pet. Resp. at 9-10.

with vomit around his mouth and nose and having difficulty breathing, he is not documented to have been "unresponsive;" the unresponsiveness that characterizes encephalopathy is marked by a significantly decreased level of consciousness featuring a decreased or absent response to stimuli. Pet. Ex. 9 at 2, 5; 42 C.F.R. §§ 100.3(b)(2)(i)(A), 100.3(b)(2)(i)(D)(1). Petitioners' expert, Dr. Bernstein, has never diagnosed A.T.W. with encephalopathy or suggested that he displayed symptoms consistent with encephalopathy.

The symptoms that A.T.W. may have exhibited following vaccination – sleepiness and feeding changes – have been explicitly identified by the Vaccine Table as insufficient to indicate encephalopathy. 42 C.F.R. § 100.3(b)(2)(i)(E); see also Marlow v. Sec'y of Health and Human Servs., No. 90-701V, 1991 WL 202226 at \*4 (Fed. Cl. Spec. Mstr. Sept. 20, 1991) (holding that a SIDS death was not attributable to encephalopathy from DPT vaccination where there was an intervening period of normal behavior including a period of fussiness, irritability, screaming, and vomiting).

Petitioners' bare assertions are insufficient to meet their burden. Accordingly, the undersigned finds that Petitioners have failed to prove that A.T.W. suffered from encephalopathy, as defined by the Table, or that A.T.W.'s death was a sequela of such encephalopathy.

## B. Off-Table Injury

Petitioners also argue an alternative off-Table injury theory of causation. The undersigned finds that Petitioners' theory of causation-in-fact fails because Petitioners' expert has not advanced a medical theory that connects A.T.W.'s death to the vaccinations A.T.W. received.

## 1. Althen Prong 1

The first prong of *Althen* requires Petitioners to set forth a scientific or medical theory to demonstrate that the vaccination can cause the type of injury A.T.W. suffered. *Althen*, 418 F.3d at 1278. The undersigned finds that Petitioners have not provided a sound or reliable medical theory causally connecting the A.T.W.'s vaccinations with his death later that evening. The undersigned acknowledges that Petitioners' expert, Dr. Bernstein, believes that the administration of multiple vaccines at once was a "possible" cause of A.T.W.'s death, and that, in his pediatric practice, he limits the number of vaccines given to a child at once. Pet. Ex. 15 at 2. The undersigned finds, however, that Dr. Bernstein's belief has little evidentiary value in the absence of a medical explanation. Dr. Bernstein provides no theory that specifically explains how any of the vaccinations that A.T.W. received could have caused A.T.W.'s death.

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<sup>&</sup>lt;sup>7</sup> The undersigned repeatedly warned Petitioners' counsel that Dr. Bernstein's reports were inadequate to prove causation. *See* procedural history, *supra*, at 2-3.

The single article submitted in support of Dr. Bernstein's report merely demonstrates a correlation between the number of vaccine doses on a nation's immunization schedule and the nation's infant mortality rate. *See generally* Pet. Ex. 17. This article fails to document any causal link between multiple vaccinations and an infant's death or SIDS. These mere generalized possibilities, with no explanation of how vaccines can cause injuries that progress to the point of death, are wholly insufficient as a medical theory proving the vaccines caused-in-fact A.T.W.'s death.

For these reasons, Petitioners' claim fails to meet the first prong of *Althen*. No further analysis under *Althen* is required, as Petitioners must meet all prongs in order to successfully establish a claim to entitlement under the Program.

#### **CONCLUSION**

Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. 42 U.S.C. § 300aa-13(a)(1). Rather, the petition must be supported by either medical records or by the opinion of a competent physician. *Id.* In this case, because there are insufficient medical records supporting Petitioners' claim, a medical expert opinion must be offered in support, establishing either the existence of a Table Injury, or, in the alternative, a sound and reliable medical theory linking vaccination to injury, and demonstrating a logical sequence of cause and effect between said vaccination and injury. Petitioners' expert has offered no such opinion.

Under the law, the undersigned can authorize compensation only if a medical condition or injury either falls within one of the Table Injury categories, or is shown by medical records or a competent medical opinion to be vaccine-caused. *See Lombardi v. Sec'y of Health and Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011) (affirming a special master's dismissal of a petition where the petitioner could not establish that she had any of the three diagnoses alleged). No such proof exists in the record. **Thus, this case is dismissed for insufficient proof. In the absence of a timely-filed motion for review of this decision (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.** 

IT IS SO ORDERED.

s/Lisa D. Hamilton-Fieldman Lisa D. Hamilton-Fieldman Special Master